

## AMENDMENTS TO THE CLAIMS:

The listing of claims will replace all prior versions, and listings, of claims in the application:

### LISTING OF CLAIMS:

1. (Previously presented) A method for measuring body temperature while regulating the temperature of at least a portion of a patient using a heat exchange catheter inserted into a lumen of the patient's body, the heat exchange catheter having conduits that enable circulation of a heat exchange medium between a heat exchange portion of the catheter and a heating/cooling apparatus for adding or removing thermal energy from the heat exchange fluid, the heating/cooling apparatus controlled by a controller, comprising:

providing a temperature probe to measure the temperature of the fluid circulating through the lumen of the patient's body, the temperature probe providing a signal representative of the temperature of the fluid circulating through the lumen of the patient's body to the controller;

circulating fluid under control of the controller between the heat transfer catheter and the heating/cooling apparatus;

stopping the flow of heat exchange medium through the heat exchange catheter for a selected period of time;

analyzing the signals received from the temperature probe while the flow of heat exchange medium is stopped and determining an estimated temperature of the fluid circulating through the lumen of the patient's body from the rate of change of the temperature while the flow of heat exchange medium is stopped;

comparing the determined temperature to a target temperature;

re-starting the flow of heat exchange medium through the heat transfer catheter;  
and

controlling the heating/cooling apparatus in accordance with the comparison to controllably add or remove thermal energy from the heat exchange fluid to heat or cool the fluid circulating through the lumen of the patient's body to heat or cool the fluid circulating through the lumen of the patient's body to the target temperature.

2. (Original) The method of claim 1, wherein the temperature probe is inserted near the heat transfer catheter in the patient.

3. (Previously presented) The method of claim 1, wherein interrupting heat exchange medium flow between the heat exchange unit and the heat transfer catheter is controlled by stopping a fluid pump within the master control unit.

4. (Previously presented) The method of claim 1, wherein interrupting heat exchange medium flow between the heat exchange unit and heat transfer catheter is controlled by diverting the heat exchange medium into a diversion pathway, stopping fluid flow from the heat exchange unit to the heat transfer catheter.

5. (Previously presented) The method of claim 4, wherein a diverter unit having a diverter valve diverts the heat exchange medium into the diversion pathway, periodically stopping the fluid circulation within the heat transfer catheter.

6. (Original) The method of claim 4, wherein the master controller is controlled by a microprocessor responsive to a plurality of patient sensors supplying patient data to the processor to control the heater/cooler unit and the diverter valve.

7. (Original) The method of claim 1, wherein the temperature probe provides responsive patient data to the processor.

8. (Previously presented) The method of claim 1, wherein the master controller processor compares signals from at least two of a plurality of sensors and either adds heat or adds cooling or stops fluid flow within the heat exchange unit.

9. (Previously presented) The method of claim 1, wherein interrupting the fluid flow between the heat transfer catheter and the heat exchange unit allows the temperature

measurements to level off in a heating/cooling region in the fluid circulating through the lumen of the patient's body near the temperature probe and the heat transfer catheter.

10. (Previously presented) A method for measuring body temperature while regulating the temperature of at least a portion of a patient, comprising:

inserting into the patient a temperature probe having sensors to measure the temperature of the patient;

providing a disposable heat transfer catheter and heat exchange unit coupled via conduits and a diverter unit that enable controlled circulation of a heat exchange medium therebetween;

providing a master control unit housing a microprocessor and a heater/cooler unit within;

installing the heat exchange unit into the master control unit and into thermal communication with the heater/cooler unit;

inserting the heat transfer catheter into the patient;

circulating fluid between the heat transfer catheter and heat exchange unit, therein transferring heat between the heat exchange unit and the heater/cooler unit so as to regulate the temperature of the patient via the heat transfer catheter;

periodically interrupting fluid flow ~~from~~ between the heat transfer catheter and the heat exchange unit by diverting the heat exchange medium between the heat exchange unit and heater/cooler unit and bypassing the heat transfer catheter;

analyzing the signals received from the temperature probe while the flow of heat exchange medium is interrupted and determining an accurate core body temperature from the rate of change of the temperature while the heat exchange medium is interrupted; and

re-starting the flow of heat exchange medium between the heat transfer catheter and the heat exchange unit.

11. (Original) The method of claim 10, wherein the temperature probe is inserted near the heat transfer catheter in the patient and provides responsive patient data to the microprocessor.

12. (Original) The method of claim 10, wherein the diverter unit comprises a diverter valve that interrupts fluid flow between the heat transfer catheter and the heat exchange unit when the valve is activated.

13. (Original) The method of claim 12, wherein activation of the diverter valve rotates a vane from a flow through orientation to a diversion orientation, sealing the heat transfer catheter inflow/outflow lines.

14. (Previously presented) The method of claim 12, wherein the controller activates the diverter valve for a predetermined time.

15. (Previously presented) The method of claim 12, wherein the controller activates the diverter valve until the temperature sensor reads the same temperature for a predetermined period of time.

16. (Previously presented) The method of claim 12, wherein the controller activates the diverter valve based on a previously determined rate of temperature change.

17. (Previously presented) The method of claim 10, wherein the microprocessor determines a temperature of the patient's body after the temperature measured by the temperature probe achieves equilibrium with the temperature of the patient's body during the periodic interruption of fluid flow.

18. (Previously presented) The method of claim 10, further comprising generating a predictive heating/cooling curve from the measured core body temperature.

19. (Original) The method of claim 10, wherein the diverter unit is a flow actuated valve installed in the heat exchange fluid flow stream between the heat transfer catheter and the heat exchange unit to control the fluid circulation path.

20. (Original) The method of claim 19, wherein the periodic fluid flow interruption stops fluid circulation when a rotating member of the flow actuated valve rotates into a short circuit orientation, stopping fluid circulation to the heat transfer catheter.

21. (Original) The method of claim 19, wherein the periodic fluid flow interruption stops flow for a predetermined time, until an electrical contact mounted on the rotating member engages an electrical contact pad, thereby sending the sensed temperature signal to the controller.

22. (Previously presented) A heat transfer catheter system, comprising:

a heat transfer catheter insertable into a patient;

a disposable heat exchange unit having a fluid pathway therewithin and incorporating an integral pump head adapted to move fluid through the fluid pathway;

conduits coupled to the heat transfer catheter and heat exchange unit that enable circulation of a heat exchange medium therebetween upon operation of the pump head;

a diverter unit that periodically redirects the fluid pathway, bypassing the heat transfer catheter; and

a reusable master control unit having a heater/cooler and a pump driver, the disposable heat exchange unit being adapted to couple to the master control unit such that the pump driver engages the integral pump head and so that the fluid pathway is in thermal communication with the heater/cooler, the control unit controlling the diverter unit to periodically interrupt fluid circulation within the heat exchange unit and the heat transfer catheter, the control unit configured

to receive a target temperature input and a sensor signal from a temperature sensor,

to analyze the signals from the sensor during the fluid flow interruption to determine a rate of change of the temperature as a function of time,

to compare the determined temperature to a target temperature,

to restart the flow of heat exchange medium through the heat transfer catheter,  
and

to control the rate at which the patient temperature approaches the target temperature by controlling the heating/cooling apparatus with proportional integrated differential (PID) responses.

23. (Original) The system of claim 22, wherein the diverter unit is a diverter valve activated by the controller.

24. (Original) The system of claim 22, wherein the diverter unit is a flow actuated valve.

25. (Original) The system of claim 24, wherein the heat exchange unit comprises two layers, a stiff back plate and a thinner heat exchange layer bonded thereto, the pattern of bonding between the two layers defining a serpentine pathway.

26. (Original) The system of claim 25, wherein the master control unit defines a cavity into which the heat exchange unit couples, wherein fluid flow through the serpentine pathway causes inflation of the thinner heat exchange layer relative to the stiff back plate and subsequent compressive retention of the heat exchange unit within the cavity.

27. (Original) The system of claim 22, wherein heater/cooler comprises a thermoelectric heater/cooler.

28. (Original) The system of claim 22, further including a plurality of sensors supplying patient data to the master control unit, the master control unit being adapted to operate the heater/cooler based on the supplied patient data.

29. (Original) The controller of claim 28 wherein the master control unit comprises a microprocessor responsive to each of the sensors to control the heater/cooler, wherein the microprocessor is configured to compare the signals from at least two of the plurality of sensors and produce an alarm condition when the signals do not agree.

30. (Canceled)

31. (Previously presented) A method for measuring body temperature while regulating the temperature of at least a portion of a patient using a heat exchange catheter inserted into a lumen of the patient's body, the heat exchange catheter having conduits that enable circulation of a heat exchange medium between a heat exchange portion of the catheter and a heating/cooling apparatus for adding or removing thermal energy from the heat exchange fluid, the heating/cooling apparatus controlled by a controller, comprising:

measuring the temperature of the patient using a temperature probe, the temperature probe providing a signal representative of the temperature of the patient to the controller;

circulating fluid under control of the controller between the heat transfer catheter and the heating/cooling apparatus so as to regulate the temperature of patient;

sampling a plurality of temperature signals received by the controller during a selected interval;

analyzing the plurality of temperature signals received from the temperature probe during the selected interval to determine a peak temperature occurring during the selected interval;

comparing the determined peak temperature to a target temperature; and

controlling the heating/cooling apparatus in accordance with the comparison to controllably add or remove thermal energy from the heat exchange fluid to heat or cool the fluid circulating through the lumen of the patient's body so that the determined peak temperature occurring during the selected interval approaches the target temperature.

32. (Previously presented) The method of claim 31, wherein analyzing the temperature signals includes:

determining the highest temperature value sampled within a selected range of the selected intervals and storing that determined value in a memory of the controller,

incrementing the selected range of selected intervals a selected number of times and, after each incrementing, repeating determining the highest temperature value sampled within the incremented selected range of selected intervals and storing that value, and

calculating the peak temperature value from the stored determined values.

33. (Previously presented) The method of claim 31, wherein analyzing the temperature signals includes:

determining the lowest temperature value sampled within a selected range of the selected intervals and storing that determined value in a memory of the controller,

incrementing the selected range of selected intervals a selected number of times and, after each incrementing, repeating determining the lowest temperature value sampled within the incremented selected range of selected intervals and storing that value, and

calculating the peak temperature value from the stored determined values.

34. (Original) The method of claim 32, further comprising:

calculating an offset value; and

adding the offset value to the peak temperature before comparing the peak temperature to the target temperature.

35. (Original) The method of claim 34, wherein calculating the offset value includes calculating a static offset value.

36. (Original) The method of claim 34, wherein calculating the offset value includes calculating a dynamic offset value.

37. (Original) The method of claim 36, wherein calculating a dynamic offset value includes calculating the dynamic offset as follows:

$$Offset_{RT} = \frac{Offset_{Calc} \bullet \ln|\Delta PF_{RT}|}{\ln|\Delta PF_{Calc}|} \quad \text{where:}$$



$Offset_{RT}$ =Dynamic real time offset

$Offset_{Calc}$ =Offset calculated when flow stopped; calculated as:

$$Offset_{Calc} = T_{Core} - T_{Peak} \text{ where:}$$

$T_{Core}$ = Temperature sensed after flow is stopped for a selected period and sensed temperature equilibrium is reached

$T_{Peak}$ =Temperature sensed just before flow is stopped

$\Delta PF_{RT}$ =Real time temperature differential between an instantaneous peak sensed blood temperature and the corresponding instantaneous temperature measurement of the heat exchange fluid

$\Delta PF_{Calc}$ =Temperature differential between the peak blood temperature sensed just before flow stoppage and the corresponding temperature of the heat exchange fluid measured at the same time.

38. (Previously presented) A system for regulating the temperature of at least a portion of a patient's body, comprising:

a heating/cooling apparatus;

a heat exchange catheter for insertion into a lumen of the patient's body, the heat exchange catheter having conduits that enable circulation of a heat exchange medium between a heat exchange portion of the catheter and the heating/cooling apparatus for adding or removing thermal energy from the heat exchange medium;

a temperature sensor disposed in the lumen downstream of the heat exchange catheter for providing temperature signals representative of the temperature of body fluid flowing through the lumen; and

a controller including a processor and a memory, the processor capable of being programmed by software to

sample the temperature signals at a selected interval,

determine a selected temperature value sampled within a selected range of the selected intervals and store that determined value in a memory of the controller,

increment the selected range of selected intervals a selected number of times and, after each increment, repeating determining the selected temperature value sampled within the incremented selected range of selected intervals and store that value, and

calculate a peak temperature value from the stored determined values, the controller responsive to the calculated peak temperature value to control the heating/cooling apparatus to add or remove thermal energy from the heat exchange medium.

39. (Canceled)

40. (Previously presented) The system of claim 38, wherein the temperature sensor is configured to move within the lumen in response to the flow of body fluid within the lumen.

41. (Canceled)